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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/074,116 | 02/12/2002 | German A. Valcarce | 101141-12 | 8300 |
| 27387 | 7590 | 03/12/2004 | EXAMINER | |
| BRUCE LONDA NORRIS, MC LAUGHLIN & MARCUS, P.A. 220 EAST 42ND STREET, 30TH FLOOR NEW YORK, NY 10017 | | | | WEBER, JON P |
| ART UNIT | | PAPER NUMBER | | |
| | | 1651 | | |

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/074,116 | VALCARCE, GERMAN A. |
| | Examiner | Art Unit |
| | Jon P Weber, Ph.D. | 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 January 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16 and 23-28 is/are pending in the application.
 4a) Of the above claim(s) 4-16 and 23-28 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-3 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 12 February 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 2/12/02.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

Status of the Claims

Claims 1-16 and 23-28 have been presented for examination.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-3 in the Paper filed 13 January 2004 is acknowledged. The traversal is on the ground(s) that the method of Group II can be practiced with the extract Group I. Similarly, the extract of Group I is the starting point for the purification methods of Groups VI and VII. This is not found persuasive because simply finding some relationship between the groups is insufficient basis for establishing lack of patentable distinctness. In this case distinctness was established because of the scope of the claims, burden was established by the separate classification and the separate searches that would be entailed. It is clear that at least some point in the purification of any enzyme, some form of cell-free extract is prepared. However, a crude cell-free extract will contain a myriad of enzymes and other active ingredients that at one time resided within the living biological cell. The mere fact that this is a starting point for the several processes only illuminates the diverse directions that a skilled artisan could take a crude cell-free extract. Doubtless, a skilled artisan could take such an extract in many other directions as well.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-16 and 23-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Information Disclosure Statement

The information disclosure statement filed 12 Feb 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but all of the information referred to therein has not been considered. In particular, Fox et al. (1998) was allegedly filed in grandparent application 09/641,609. However, this reference is not cited on any 1449 or 892 in said application, Fox et al. (1998) is not listed on the published patent US 6,534,100, and no copy can be found in our file. In parent application 09/835,804, a 1449 citing Fox et al. (1998) is present and initialed, and the reference is printed on the published patent US 6,391,351. However, it was alleged at the time of filing, 03 Jan 2002, of the IDS in 09/835,804 listing Fox et al. that a copy of the reference had been filed in the parent application 09/641,609 and that none was available to the inventors at that time, and therefore none was provided. None was found in the file either. Since it has been established *supra* that there is no evidence that Fox et al. was filed in 09/641,609, Fox et al. cannot be considered.

Claim Objections

Claims 1-2 are objected to because of the following informalities: the claim refers to “Ciliate phylum” or “*Ciliata* phylum” which is not art accepted terminology. “*Phylum Ciliata*” is suggested. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for obtaining extract with Δ-7 and Δ-22 desaturase activity from *Paremecium*, *Tetrahymena* and *Copidium*, does not reasonably provide enablement for and Phylum Ciliata microorganism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The presence or absence of an enzyme activity in a particular microorganism is difficult to predict. Given the extremely broad nature of the classes, families and species encompassed by the claim to “*Phylum Ciliata*” a person of ordinary skill in the art would be surprised that all or even most of the organisms within this phylum contained the claimed activities. As pointed out in Mallory et al. (1970) sterols are not found in *Tetrahymena* in the absence of exogenous sterols in the medium. Hence, it was a surprise that these organisms could metabolize these sterols. Further it was remarked that these organisms are incapable of *de novo* synthesis of sterols.

Accordingly, there is reason to doubt that all or even most of the organisms within this broad phylum contain these two enzyme activities.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertram et al. (1981).

Bertram et al. (1981) disclose a cell-free extract from *Tetrahymena thermophila* that contains an enzyme that desaturates stearoyl-CoA to octadecanoic acid. The cell-free extract is the microsomal fraction (page 127, column 2). This is an inherency rejection. Whether Bertram et al. (1981) recognized that their extract contained the claimed activities or not does not materially change the fact that they obtained a cell-free microsomal fraction from a *Tetrahymena* ciliate.

Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily results in the claimed process as opposed to a possibility. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward

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chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

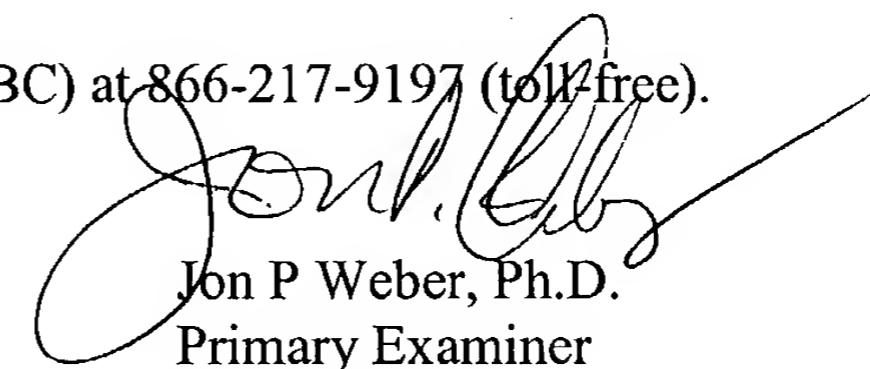
In the instant case, since the same claimed composition is obtained, if it failed to have the claimed activity, neither would the instant extract. Hence, clearly criterion 1 and 2 are met. Given the teachings of Mallory et al. (1970) that tetrahymena can introduce Δ -7 and Δ -22 double bonds into sterols, a person of ordinary skill in the art would reasonably expect that extracts from this organism would contain an enzyme capable of introducing such double bonds. Hence, criterion 3 is met.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
11 March 2004